



**AdvaMed**

Advanced Medical Technology Association

# **Enhancing Medical Device Sector Innovation and Market Access Through Voluntary Codes of Business Ethics in Asia and Latin America**

## **Broader Pacific Dialogue**

Wednesday, April 17, 2013

San Jose, Costa Rica

**Christopher White**

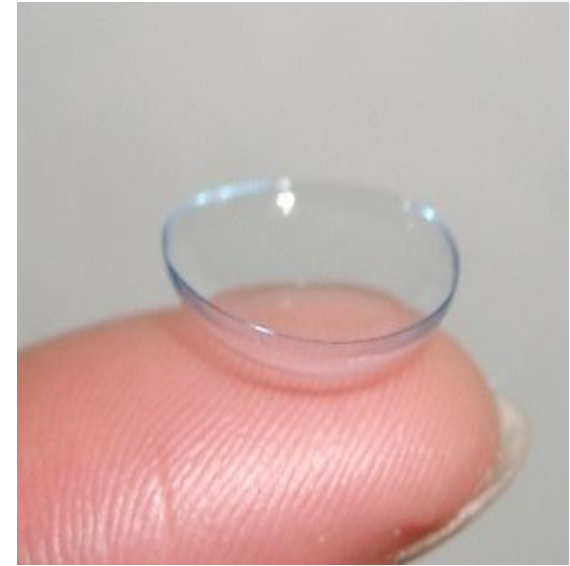
Senior Executive Vice President & General Counsel  
The Advanced Medical Technology Association

# Who is AdvaMed?

## Mission

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

# What are Medical Devices?



# What are Medical Devices?

## Unique Characteristics of Medical Devices and Diagnostics

- Vast majority of companies are smaller – often the incubators for most cutting – edge innovations
- 18 month average life-cycle of Medical Devices
- Incremental improvements made over time
- Replace or augment a bodily function; typically local effects
- Diverse family of products. Any single generation may be distributed to small or niche patient population.
- Technical and technique specific training required for safe and effective use

# Medical Device Industry's Unique Business Ethics Needs

- Close and ongoing collaboration with health care professionals are:
  - Essential to medical product innovation and development
  - Critical to training for safe and effective use of medical devices
- Ethical arrangements are needed to:
  - Ensure products selected are in best interest of patients
  - Protect public trust in health care delivery
  - Promote Innovation

# Current state

- “It is difficult to know the right thing to do.”
- Why?
  - Different jurisdictions
  - Different legal systems
  - Different healthcare systems
  - Different cultures
  - Different accepted business practices

# AdvaMed Code as a Tool to Promote Ethical Business Practices

- Encourages voluntary, ethical interactions between Medical Device Manufacturers & Health Care Professionals
- Distinguishes between interactions that:
  - Advance Medical Technology
  - Have Potential to Influence Medical Decision- Making Inappropriately

## Code Addresses:

- Arrangements w/ Consultants; Royalties
- Member-Sponsored Product Training & Education
- Supporting Third Party Educational Conferences
- Sales & Promotional Meetings
- Demonstration Units; Evaluation Products
- Provision of Reimbursement & Other Economic Information
- No Entertainment; Recreation; Gifts
- Grants & Charitable Donations



### CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

#### I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States ("Health Care Professionals").

#### Medical Technologies

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

#### Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health

# A Self Regulatory Approach to Ethical Interactions

## Challenges to Self Regulatory Approach to Business Ethics

- Device Development & Collaborations are Global
- Rapid Global Dispersion of Breakthrough Medical Technologies
- “Glocalization:” small local companies have early foreign sales in unfamiliar legal jurisdictions
- **But** ... fragmented patchwork of Ethical Codes (where they exist) Causes Uncertainty & Unpredictability



# Ethical Business is a Global Commitment

## Global Statement on Ethical Interactions

May 2010

### Core Principles:

- Appropriateness
- Transparency
- Legitimacy
- Independence



#### GLOBAL STATEMENT ON ETHICAL INTERACTIONS BETWEEN MEDICAL TECHNOLOGY COMPANIES AND HEALTHCARE PROFESSIONALS

May 19, 2011

Medical technology industry Codes of Ethics and Business Practice support and promote ethical interactions among medical device and diagnostics companies ("Companies") and Healthcare Professionals ("HCPs") in order to assure ongoing development of advanced medical technologies and patient access to the safe and effective use of medical technologies.

Healthcare and medical technology innovation increasingly extends beyond national and cultural boundaries, and there is a growing need to promote internationally a culture in Companies' interactions with HCPs based on common high ethical principles.

Even though different in their wording and in some detailed points, industry codes share the same goals and spirit. They promote the principles of:

- Legitimacy,
- Transparency,
- Independence and
- Appropriateness of relationships between Companies and HCPs.

These ethical standards are illustrated with practical guidance on structuring appropriate arrangements, such as:

- Research and Development to advance medical science, develop new technologies, improve existing products and services, and enhance the quality and efficacy of care for patients. Through consultancy agreements with Companies, HCPs are engaged in, for example, product research and development and clinical trials.
- Education of HCPs, for example through support to third-party educational programs and educational grants;
- Training HCPs on device deployment, use and application to facilitate the safe and effective use of medical technologies by HCPs; and
- Providing donations for charitable or other philanthropic purposes to support *bona fide* charitable organizations and missions.

Ethical behaviour is a prerequisite for continued professional collaborations necessary to the ongoing advancement of medical technology and to the appropriate use of medical technologies in healthcare systems in the best interest of the patient. It is critical that these medically beneficial and collaborative interactions among Companies and HCPs preserve independent

# Global Code Harmonization

Kuala Lumpur



Asia-Pacific  
Economic Cooperation

- Public Private Partnership
  - Industry Specific
  - Region Wide Adoption
  - Voluntary; Self Regulatory
- Kuala Lumpur Principles Medical Device Sector Codes of Ethics

2011/SMEMM/009

Agenda Item: 3



# Americas Wide Opportunity

Provide greater clarity and consistency among business codes of ethics across the Americas



Develop harmonized business code of ethics principles for the medical device sector



# Code Harmonization in Latin America

## Substantial Progress through Americas Competitiveness Forum: Senior-level support from U.S., Panama, Chile, Colombia, Paraguay, Peru, and Mexico



### Medical Device Sector Innovation, Trade, and Ethics: Advancing a Regional Sector-Based Approach to the Corruption Challenge

October 24, 2012

- 1:45-2:00 REGISTRATION: *Convention Center, Cali, Colombia*
- 2:00-2:20 WELCOME COMMENTS:
- Walter Bastian, Deputy Assistant Secretary of Commerce, USA
  - Stephen Ubi, President & Chief Executive Officer, AdvaMed, USA
- 2:20-2:40 OVERVIEW: Enhancing Medical Device Sector Innovation and Market Access Through Voluntary Codes of Business Ethics
- Lynn Costa, Senior Trade Development Advisor, International Trade Administration, U.S. Department of Commerce, USA
  - Christopher White, Senior Executive VP, General Counsel, AdvaMed, USA
- 2:40-3:15 AN ASIAN PERSPECTIVE: Kuala Lumpur Principles and Harmonized Medical Device Codes in APEC
- Dato' Hj. Binti Sutimah Sutan, Deputy Chief Commissioner, Anti-Corruption Commission, Malaysia
- 3:15-4:00 LATIN AMERICAN PERSPECTIVES:  
Overcoming International Business Challenges
- Mario Mongiardi, President, COMSULAD, Peru
- Harmonizing Business Practices through Public-Private Partnership
- Andres Perez Figueroa, Baxter Healthcare, Mexico
- Working with Latin American Leaders on the Issues
- Carlos Motta, Government Affairs, Covidien, Colombia
- 4:00-4:45 GLOBAL & REGIONAL PERSPECTIVES:
- Moderator: Kelly Phillips, VP, Chief Counsel, Boston Scientific, USA
  - Norm Finch, VP, Associate General Counsel & Global Chief Compliance Officer, Zimmer, USA
  - Daniel Garren, Senior VP & Chief Compliance Officer, Wright Medical Technology, USA
  - Santiago Rabassa, General Counsel, Latin America, Covidien, USA
- 4:45-5:00 CLOSING: MEDICAL DEVICE INNOVATION, INTEGRITY & THE ACF ETHICS INITIATIVE THROUGH ACF VII IN PANAMA
- Dr. Ruben Berrocal, National Secretary, Secretariat of Science, Innovation and Technology, Panama [INVITED]
  - Christopher White, Senior Executive VP, General Counsel, AdvaMed, USA





# 2013 AdvaMed- ALDIMED MOU

## Emphasizes Device Industry Cooperation on Ethics Across the Americas

### MEMORANDUM OF UNDERSTANDING FOR DEFINED POLICY ACTIVITIES BETWEEN ADVAMED AND ALDIMED

#### PURPOSE

The Association of Latin American Medical Device Industry (ALDIMED)<sup>1</sup> and the Advanced Medical Technology Association (AdvaMed) are industry associations representing manufactures of medical technology in the Americas.<sup>2</sup> Both parties support the creation of economic conditions that enhance innovation in the medical technology industry and intend to develop and expand cooperation on policy issues of mutual interest. The objective of this Memorandum of Understanding (MOU) is to establish an initial set of issues for joint understanding and work. The relationship between the associations will be based on principles of mutual respect, cooperation, coordination and transparency.

#### Trade Policy

AdvaMed and ALDIMED recognize that the expansion of trade and investment, including through the reduction of barriers and the fostering of an open and predictable environment for international trade and investment, can promote innovation and economic growth and development. The Parties will use every available opportunity, including in the ACF, to encourage their governments to further open markets and provide protection for investments.

#### Intellectual Property

ALDIMED and AdvaMed recognize the critical role creative ideas play in innovation and that those ideas need to be rewarded through sound laws to protect intellectual property. The Parties also recognize that counterfeit medical technology can undermine patient safety and discourage innovation. The Parties will support international agreements and actions that provide protection for intellectual property and discourage counterfeits.

#### Ethical Business Practices

As healthcare and medical technology innovation extends beyond national and cultural boundaries, there is a growing need to promote internationally a harmonized environment of ethical business conduct among company representatives and healthcare professionals. ALIMED and AdvaMed share common goals to encourage adherence to an agreed set of ethical business practices. To that end, AdvaMed and ALDIMED plan to develop *Principles for Ethical Business Practices in the Medical Technology Industry* to recommend to medical technology associations in each of the members active in the Americas Competiveness Form (ACF) to adopt in their respective countries.

#### Regulatory Convergence

AdvaMed and ALDIMED recognize the need for regulations that ensure the safety and effectiveness of medical technology for patients in all countries. The Parties also believe that redundant and unnecessary regulations delay patient access and increase costs. They see that

<sup>1</sup> ALDIMED member associations include: [ABIMED, AMID, list members]

<sup>2</sup> The term "medical technology" refers to the full range of medical devices and diagnostic products used to diagnose and treat patients in hospitals and outpatient settings.

# Siemens Integrity Initiative



- Siemens has launched a global US\$100 million Siemens Integrity Initiative which will support organizations and projects that fight corruption and fraud through:
  - Collective Action -
    - Raise compliance standards and create awareness by creating alliances between the public and the private sector
  - Education & Training –
    - Build capacity, foster a culture of integrity and promote knowledge sharing between institutions and stakeholders
- Eligibility - Application for funds from the Siemens Integrity Initiative is open to non-profit organizations.

**SIEMENS**  
Siemens Integrity Initiative  
Creating fair market conditions  
Fighting corruption and fraud through collective action, education & training

Expression of Interest – funding round December 9, 2009

**1. Summary**

Project name:	
Name of applicant:	
Category of application:	<input checked="" type="checkbox"/> Collective Action <input type="checkbox"/> Education & Training
Total amount of funding required: (in USD)	
Intended start of project: (month/year)	
Planned project duration: (number of months)	
Countries covered:	
Business Sectors covered**:	
Main contact for this application: Name, title, phone, e-mail	

\* In case of joint applications, specify the organization assuming the leading position; see Annex 1 for supporting information regarding all organizations participating in the project.  
\*\* For example: Healthcare, Energy, Industry, or others.

**2. Organizations participating in the project:**  
List the names of all organizations that will participate in the implementation of the project and their respective role:

Name of organization	Role in project
1.	
2.	
3.	
4.	
5.	

**IMPORTANT!** For EACH organization participating in the project, fill out Annex 1 and submit it with the Expression of Interest form together with the required supporting documentation.

**Joint applications:** Where several organizations plan to implement the project jointly, an outline of the (planned) split of responsibilities/ work share must be given here:



# Siemens Integrity Initiative

- A Joint Proposal
  - Unique partnership among national governments and industry trade associations across the Americas to achieve harmonized codes of ethics for the medical device sector to foster innovation and patient access.
  - Key Objectives:
    - 1) Establish harmonized, high-standard codes of ethics among the western hemisphere's large and small medical device sector associations and member companies;
    - 2) Support long-term viability of these codes by expanding the number of ethics compliance trainers and by providing the necessary educational resources to establish low-cost compliance programs;
    - 3) Promote local collaborations on ethics awareness and the importance of enforcement between industry and key sector stakeholders, such as regulators, physicians, and hospitals; and
    - 4) Build a lasting, multi-regional network of ethics compliance practitioners between APEC and ACF economies.

# Siemens Integrity Initiative – A Joint Proposal

- Key Activities- workshops and public-private programs and meetings to:
  - 1) First establish an Americas-made source of industry ethical principles;
  - 2) Establish industry-specific codes aligned with the principles;
  - 3) Achieve local government and stakeholder support; and
  - 4) Train compliance and government officials on the codes and compliance.



# Siemens Integrity Initiative – A Joint Proposal

	KEY MILESTONES
2013	Develop ACF Principles for Voluntary Codes of Business Ethics in the Medical Device Sector
Oct. 2013	ACF Principles endorsed by ACF Leaders and Trade Ministers along with a recommendation that (A) sector associations and companies to develop aligned codes of ethics and (B) key stakeholders engage with the sector in collaborations to promote ethical business practices.
Spring 2014	The ACF region's medical device sector associations and companies have begun drafting or aligning codes of ethics with the ACF Principles.
June 2015	The majority of associations and companies complete their codes through an intensive monitoring and support process.
Summer 2015	Completion of a Train-the-Trainer Workshop in Brazil that provides educational resources to industry associations and companies (with aligned codes of ethics) so they may implement local trainings and establish low-cost, sustainable compliance programs.
Fall 2015	Non-industry stakeholders in the ACF region's medical device sector - including government regulators, physicians, and hospitals – are brought into the project through an awareness building workshop; local action plans are developed to collaborate with industry and foster ethical ecosystems.
Fall 2016	Completion of an ACF and APEC advanced training session to (1) build a multi- regional network of ethics compliance trainers, (2) address training challenges and solutions, and (3) establish an online resource center to foster the exchange of information and communication between ACF and APEC compliance trainers.

**Therefore,  
Ethics = Good business.**

$$(E=gb)^2$$

# ***Questions?***

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